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Docket No.: 05983/100G123-US2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Mary K. Crow

Application No.: 10/088,319 Confirmation No.: 1541

Filed: September 18, 2002 Art Unit: 1644

For: ALTERED NUCLEOTIDE SEQUENCE IN CD40 LIGAND PROMOTER Examiner: P. Gambel

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Restriction Requirement mailed May 4, 2006, a Petition for an Extension of Time for one month up to and including July 4, 2006 and the required fee being filed concurrently herewith, applicants provisionally elect the invention of Group I, claims 1-3 for prosecution with the above-identified application with traverse.

Applicants respectfully submit that the invention of Groups I-V have a special technical feature that defines the contribution over each of the references cited below by the Examiner.

The reasons for traversal are as follows:

The Examiner contends that Li[1] et al. (*Arthritis and Rheumatism* 42(6): 1291-1296, 1999)(hereafter "Webster") discloses the same or nearly the same altered nucleotide sequence in the

[1] Applicants believe that the Examiner intended to refer to the article by Webster et al. having the citation of *Arthritis and Rheumatism* 42(6): 1291-1296, 1999.

immediate promoter region of CD40 ligand that is associated with rheumatoid arthritis as encompassed by the instant claims. Applicants traverse.

Applicants respectfully submit that the invention of Groups I-V have a special technical feature that defines the contribution over Webster. The difference between the pending claims and Webster is the specific location of sequence variability for the gene encoding the CD40 ligand. As described in the instant specification on page 13, lines 15-31 to page 14, lines 1-8, sequence variability is discussed with respect to the DNA promoter region that affects transcription of the mRNA for the CD40 ligand. Webster, in the paragraph spanning pages 1293 and 1294 and the second full paragraph in column one of page 1294, describes a coding mutation that impairs the expression of the CD40 ligand rather than a variation in the promoter that might increase expression of the CD40 ligand. Therefore, the targeted gene region encoding for the CD40 ligand described by Webster and that of the instant application are different, and the difference has functional consequences. Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner invites applicants to provide the date that the co-inventors' disclosure in the September 1999 supplement issue (Li et al., *Arthritis & Rheumatism*, volume 42, issue 9, supplement, pages S1-S474)(hereafter "Li") was made available to the public.

In Exhibit 1, Applicants submit to the Examiner correspondence from Jane Diamond, the Managing Editor of *Arthritis & Rheumatism*, stating that the mailing date for Li was September 30, 1999. Applicants filed U.S. Provisional Application No. 60/153,625, from which the instant application claims the benefit of priority, on September 13, 1999. Applicants filed U.S. Provisional Application No. 60/153,625 before the mailing date of Li. Thus, Li is not available as prior art against the claims of the instant application. Applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants respectfully submit that the invention of Groups I-V have a special technical feature that defines the contribution over Gomoloka et al. (*J. Mol. Med.* 73: 19-29, 1995)(hereafter "Gomoloka"). The difference between the pending claims and Gomoloka is the specific location of

sequence variability for the gene encoding the CD40 ligand. As described in the instant specification on page 13, lines 15-31 to page 14, lines 1-8, sequence variability is discussed with respect to the DNA promoter region that affects transcription of the mRNA for the CD40 ligand. Gomoloka, in Table 1 on page 21 and in the paragraph spanning columns one and two on page 28, describes a polymorphism comprising a dinucleotide repeat in the 3' untranslated region of the CD40 ligand gene that confers variability in the stability of the CD40 ligand mRNA or that alters the efficiency of translation of the CD40 ligand mRNA. Therefore, the targeted gene region encoding for the CD40 ligand described by Gomoloka and that of the instant application are different, and the difference has functional consequences. Applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants respectfully submit that the invention of Groups I-V have a special technical feature that defines the contribution over MacDonald et al. (*J. Clin. Invest.* 100: 2404-2414, 1997)(hereafter "MacDonald"). The difference between the pending claims and MacDonald is the targeted location of the sequence for the gene encoding the CD40 ligand. As described in the instant specification on page 50, lines 10-12, primer sequences were used to amplify the 5' promoter region sequence of the CD40 ligand. MacDonald, on page 2407 in the paragraph spanning columns one and two and on page 2408, in the legend of Figure 3, describes using primer sequences to amplify the mRNA, not the promoter region, of the CD40 ligand. MacDonald does not discuss amplification of the promoter region, nor would it be possible to amplify the promoter sequence when performing PCR to detect mRNA. Therefore, the specific region of the CD40 ligand gene described by MacDonald and that of the instant application are different, and the difference has functional consequences. Applicants respectfully request reconsideration and withdrawal of this rejection.

Therefore, Applicants respectfully submit that none of the above references cited by the Examiner teach the claimed nucleic acid, vector and host cell. The invention of Group I has a special technical feature that defines the contribution over the above-cited references. In fact, Groups I-V are so linked by the same or a corresponding special technical feature as to form a

single general inventive concept and therefore Restriction is not proper, and the requirement should be withdrawn.

The Examiner contends that Applicants' priority document U.S. Provisional Application No. 60/153,615 does not provide sufficient written description for the breadth of the claims, as currently recited. Applicants respectfully disagree with the Examiner.

Support for claim 1 can be found, for example, in the priority document on page 5, Figure 1. Figure 1 of the priority document consists of the same 5' flanking sequence alignment for wild-type and altered CD40 ligand as Figure 2 of the instant application. Both alignments provide the sequence for the altered CD40 ligand recited in SEQ ID NO: 2 of claim 1 of the instant application. Claim 1 is the broadest claim pending and it encompasses the subject matter of claims 2 and 3.

Applicants convey with reasonable clarity to those skilled in the art that, as of Applicants' earliest filing date sought, they were in possession of the invention, and that the invention, in that context, is reflected by the amended claims. MPEP Section 2163.02 states: "[t]he test for sufficiency for support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter.'"citing *Ralston Purina Co. v. FarMar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985)(quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir.1983)). Furthermore, Applicants respectfully submit that the claims of a patent application are interpreted in view of the specification. As stated in Phillips v. AWH:

> "The U.S. Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction '**in light of the specification** as it would be interpreted by one of ordinary skill in the art.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (citing *In re Am. Acad. Of Sci. Tech..*, 367 F.3d 1359 (Fed. Cir. 2004) (emphasis added)).

A skilled worker would recognize from a reading of the provisional application from which priority in the instant application is claimed, that Applicants teach an isolated and purified nucleic acid having the sequence of residues 331-455 of SEQ ID NO: 2, a vector comprising the same and a cell comprising the claimed vector.

Therefore, U.S. Provisional Application No. 60/153,615, as filed, provides the necessary written support for the breadth of the claims of the instant application. Therefore, Applicants respectfully request reconsideration and withdrawal of the Examiner's objection that applicant's priority document does not provide sufficient written description for the breadth of the claims.

Issuance of a favorable office action on the merits of the pending claims is earnestly solicited.

Dated: July 5, 2006

Respectfully submitted,

By Howard M. Frankfort

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